Newborn Screening Quality Assurance Program
Acylcarnitines Quality Control Specimen Certification
Set 2— July 8, 2013
Acylcarnitines Method: MSMS Derivatized - MS/MS non-kit

ENRICHMENT LEVELS (endogenous levels not included)

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1361	0	1362	10.0	1363	20.0	1364	30.0
Acetylcarnitine (C2)	1361	0	1362	10.0	1363	20.0	1364	30.0
Propionylcarnitine (C3)	1361	0	1362	3.0	1363	7.5	1364	12.0
Malonylcarnitine (C3DC)	1361	0	1362	0.5	1363	1.5	1364	3.0
Butyrylcarnitine (C4)	1361	0	1362	1.0	1363	2.5	1364	5.0
3-Hydroxybutyrylcarnitine (C4OH)	1361	0	1362	0.5	1363	1.0	1364	2.5
Isovalerylcarnitine (C5)	1361	0	1362	0.5	1363	1.5	1364	3.0
Glutarylcarnitine (C5DC)	1361	0	1362	0.5	1363	1.0	1364	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	1361	0	1362	0.5	1363	1.5	1364	2.5
Hexanoylcarnitine (C6)	1361	0	1362	0.5	1363	1.0	1364	2.5
Octanoylcarnitine (C8)	1361	0	1362	0.5	1363	1.0	1364	2.5
Decanoylcarnitine (C10)	1361	0	1362	0.5	1363	1.0	1364	2.5
Dodecanoylcarnitine (C12)	1361	0	1362	0.5	1363	1.0	1364	2.5
Myristoylcarnitine (C14)	1361	0	1362	0.5	1363	1.5	1364	3.0
Palmitoylcarnitine (C16)	1361	0	1362	4.0	1363	8.0	1364	12.0
3-Hydroxypalmitoylcarnitine (C16OH)	1361	0	1362	0.1	1363	0.5	1364	1.0
Stearoylcarnitine (C18)	1361	0	1362	1.0	1363	2.0	1364	5.0
3-Hydroxystearoylcarnitine (C18OH)	1361	0	1362	0.1	1363	0.5	1364	1.0

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ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood□□), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	1361	$\bar{x}$ = 17.0 CL = 13.8-20.1	1362	$\bar{x}$ = 29.0 CL = 23.6-34.4	1363	$\bar{x}$ = 40.1 CL = 33.5-46.6	1364	$\bar{x}$ = 55.6 CL = 46.6-64.5
C2	1361	$\bar{x}$ = 12.4 CL = 11.2-13.7	1362	$\bar{x}$ = 21.5 CL = 18.5-24.6	1363	$\bar{x}$ = 30.5 CL = 27.1-33.9	1364	$\bar{x}$ = 40.6 CL = 36.2-45.0
C3	1361	$\bar{x}$ = 1.2 CL = 0.9-1.5	1362	$\bar{x}$ = 4.0 CL = 2.9-5.1	1363	$\bar{x}$ = 8.0 CL = 6.1-9.9	1364	$\bar{x}$ = 13.2 CL = 10.9-15.5
C3DC	1361	$\bar{x}$ = 0.0 CL = 0.0-0.1	1362	$\bar{x}$ = 0.3 CL = 0.2-0.4	1363	$\bar{x}$ = 0.8 CL = 0.6-1.1	1364	$\bar{x}$ = 1.6 CL = 1.2-2.1
C4	1361	$\bar{x}$ =0.1 CL = 0.1-0.2	1362	$\bar{x}$ = 0.9 CL = 0.7-1.2	1363	$\bar{x}$ = 2.2 CL = 1.6-2.8	1364	$\bar{x}$ = 4.4 CL = 3.4-5.5
C4OH	1361	$\bar{x}$ = 0.1 CL = 0.0-0.1	1362	$\bar{x}$ = 0.4 CL = 0.3-0.5	1363	$\bar{x}$ = 0.7 CL = 0.5-0.9	1364	$\bar{x}$ = 1.6 CL = 1.2-1.9
C5	1361	$\bar{x}$ = 0.1 CL = 0.0-0.1	1362	$\bar{x}$ = 0.5 CL = 0.3-0.7	1363	$\bar{x}$ = 1.3 CL = 1.1-1.6	1364	$\bar{x}$ = 2.7 CL = 2.2-3.2
C5DC	1361	$\bar{x}$ = 0.0 CL = 0.0-0.1	1362	$\bar{x}$ = 0.5 CL = 0.4-0.6	1363	$\bar{x}$ = 1.0 CL = 0.8-1.3	1364	$\bar{x}$ = 2.4 CL = 1.7-3.0
C5OH	1361	$\bar{x}$ = 0.6 CL = 0.5-0.7	1362	$\bar{x}$ = 1.0 CL = 0.8-1.3	1363	$\bar{x}$ = 1.8 CL = 1.4-2.2	1364	$\bar{x}$ = 2.7 CL = 2.1-3.3
C6	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.4 CL = 0.3-0.5	1363	$\bar{x}$ = 0.8 CL = 0.6-1.0	1364	$\bar{x}$ = 1.9 CL = 1.5-2.2
C8	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.5 CL = 0.4-0.7	1363	$\bar{x}$ = 1.0 CL = 0.8-1.2	1364	$\bar{x}$ = 2.4 CL = 1.9-2.9
C10	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.5 CL = 0.4-0.6	1363	$\bar{x}$ = 1.0 CL = 0.8-1.1	1364	$\bar{x}$ = 2.4 CL = 1.9-2.8
C12	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.4 CL = 0.3-0.6	1363	$\bar{x}$ = 0.9 CL = 0.6-1.2	1364	$\bar{x}$ = 2.0 CL = 1.7-2.3
C14	1361	$\bar{x}$ = 0.1 CL = 0.0-0.1	1362	$\bar{x}$ = 0.5 CL = 0.4-0.6	1363	$\bar{x}$ = 1.4 CL = 1.1-1.6	1364	$\bar{x}$ = 2.6 CL = 2.1-3.2
C16	1361	$\bar{x}$ = 0.8 CL = 0.6-0.9	1362	$\bar{x}$ = 3.5 CL = 2.7-4.3	1363	$\bar{x}$ = 7.2 CL = 6.1-8.3	1364	$\bar{x}$ = 10.5 CL = 8.9-12.1
C16OH	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.1 CL = 0.1-0.1	1363	$\bar{x}$ = 0.4 CL = 0.3-0.5	1364	$\bar{x}$ = 0.7 CL = 0.6-0.9
C18	1361	$\bar{x}$ = 0.6 CL = 0.5-0.8	1362	$\bar{x}$ = 1.5 CL = 1.2-1.9	1363	$\bar{x}$ = 2.2 CL = 1.8-2.6	1364	$\bar{x}$ = 4.8 CL = 3.9-5.7
C18OH	1361	$\bar{x}$ = 0.0 CL = 0.0-0.0	1362	$\bar{x}$ = 0.1 CL = 0.1-0.1	1363	$\bar{x}$ = 0.3 CL = 0.2-0.4	1364	$\bar{x}$ = 0.7 CL = 0.5-0.8

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality assurance in the*

newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.

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Set 2— July 8, 2013
Previous Lot Transition Materials (parallel testing)
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ENRICHMENT LEVELS (endogenous levels not included)

Analyte (μmol/L whole blood)	Lot	*Base*	*Lot*	*Low*	*Lot*	*Intermediate*	*Lot*	*High*
Free carnitine (C0)	1265	0	1266	10.0	1267	20.0	1268	30.0
Acetylcarnitine (C2)	1265	0	1266	10.0	1267	20.0	1268	30.0
Propionylcarnitine (C3)	1265	0	1266	3.0	1267	7.5	1268	12.0
Malonylcarnitine (C3DC)	1265	0	1266	0.5	1267	1.5	1268	3.0
Butyrylcarnitine (C4)	1265	0	1266	1.0	1267	2.5	1268	5.0
3-Hydroxybutyrylcarnitine (C4OH)	1265	0	1266	0.5	1267	1.0	1268	2.5
Isovalerylcarnitine (C5)	1265	0	1266	0.5	1267	1.5	1268	3.0
Glutarylcarnitine (C5DC)	1265	0	1266	0.5	1267	1.0	1268	2.5
3-Hydroxyisovalerylcarnitine (C5OH)	1265	0	1266	0.5	1267	1.5	1268	2.5
Hexanoylcarnitine (C6)	1265	0	1266	0.5	1267	1.0	1268	2.5
Octanoylcarnitine (C8)	1265	0	1266	0.5	1267	1.0	1268	2.5
Decanoylcarnitine (C10)	1265	0	1266	0.5	1267	1.0	1268	2.5
Dodecanoylcarnitine (C12)	1265	0	1266	0.5	1267	1.0	1268	2.5
Myristoylcarnitine (C14)	1265	0	1266	0.5	1267	1.5	1268	3.0
Palmitoylcarnitine (C16)	1265	0	1266	3.0	1267	8.0	1268	12.0
3-Hydroxypalmitoylcarnitine (C16OH)	1265	0	1266	0.1	1267	0.5	1268	1.0
Stearoylcarnitine (C18)	1265	0	1266	1.0	1267	2.0	1268	5.0

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ANALYTICAL INFORMATION *Lot Numbers, Mean Values ($\bar{x}$, µmol/L whole blood□□), and 95% Confidence Limits (CL)*

Analyte	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*	*Lot*	*Mean/ 95% CL*
C0	1265	$\bar{x}$ = 16.2 CL = 13.6-18.9	1266	$\bar{x}$ = 31.5 CL = 24.3-38.8	1267	$\bar{x}$ = 47.8 CL = 38.4-57.1	1268	$\bar{x}$ = 65.6 CL = 52.0-79.1
C2	1265	$\bar{x}$ = 8.1 CL = 7.2-9.0	1266	$\bar{x}$ = 16.3 CL = 14.0-18.7	1267	$\bar{x}$ = 25.3 CL = 22.9-27.8	1268	$\bar{x}$ = 33.8 CL = 30.4-37.3
C3	1265	$\bar{x}$ = 0.7 CL = 0.5-0.9	1266	$\bar{x}$ = 3.3 CL = 2.6-3.9	1267	$\bar{x}$ = 7.1 CL = 6.3-7.9	1268	$\bar{x}$ = 11.2 CL = 8.5-13.9
C3DC	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.3 CL = 0.2-0.3	1267	$\bar{x}$ = 0.7 CL = 0.6-0.8	1268	$\bar{x}$ = 1.4 CL = 1.1-1.7
C4	1265	$\bar{x}$ =0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.8 CL = 0.7-1.0	1267	$\bar{x}$ = 2.0 CL = 1.6-2.4	1268	$\bar{x}$ = 4.1 CL = 3.4-4.8
C4OH	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.2-0.5	1267	$\bar{x}$ = 0.7 CL = 0.6-0.8	1268	$\bar{x}$ = 1.8 CL = 1.3-2.2
C5	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 1.2 CL = 1.0-1.4	1268	$\bar{x}$ = 2.6 CL = 2.1-3.1
C5DC	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.3 CL = 0.2-0.4	1267	$\bar{x}$ = 0.7 CL = 0.5-0.8	1268	$\bar{x}$ = 1.8 CL = 1.5-2.2
C5OH	1265	$\bar{x}$ = 0.4 CL = 0.4-0.5	1266	$\bar{x}$ = 0.8 CL = 0.6-0.9	1267	$\bar{x}$ = 1.5 CL = 1.3-1.7	1268	$\bar{x}$ = 2.4 CL = 1.8-3.0
C6	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 0.7 CL = 0.6-0.9	1268	$\bar{x}$ = 2.0 CL = 1.6-2.4
C8	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.5	1267	$\bar{x}$ = 0.8 CL = 0.7-1.0	1268	$\bar{x}$ = 2.2 CL = 1.8-2.5
C10	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.4 CL = 0.3-0.6	1267	$\bar{x}$ = 0.8 CL = 0.7-1.0	1268	$\bar{x}$ = 2.1 CL = 1.8-2.3
C12	1265	$\bar{x}$ = 0.0 CL = 0.0-0.1	1266	$\bar{x}$ = 0.4 CL = 0.3-0.6	1267	$\bar{x}$ = 0.9 CL = 0.7-1.0	1268	$\bar{x}$ = 2.0 CL = 1.7-2.4
C14	1265	$\bar{x}$ = 0.1 CL = 0.0-0.1	1266	$\bar{x}$ = 0.5 CL = 0.4-0.6	1267	$\bar{x}$ = 1.3 CL = 1.1-1.4	1268	$\bar{x}$ = 2.5 CL = 2.2-2.9
C16	1265	$\bar{x}$ = 0.5 CL = 0.4-0.6	1266	$\bar{x}$ = 2.3 CL = 1.8-2.7	1267	$\bar{x}$ = 5.5 CL = 5.0-6.1	1268	$\bar{x}$ = 8.3 CL = 7.1-9.5
C16OH	1265	$\bar{x}$ = 0.0 CL = 0.0-0.0	1266	$\bar{x}$ = 0.1 CL = 0.0-0.1	1267	$\bar{x}$ = 0.3 CL = 0.3-0.4	1268	$\bar{x}$ = 0.7 CL = 0.5-0.8
C18	1265	$\bar{x}$ = 0.4 CL = 0.4-0.5	1266	$\bar{x}$ = 1.1 CL = 0.9-1.3	1267	$\bar{x}$ = 1.7 CL = 1.5-2.0	1268	$\bar{x}$ = 4.1 CL = 3.4-4.9

Note: The values provided in the above tables are for reference use only. The mean value and confidence limits (CL) are determined by CDC for each Quality Control (QC) lot. Each participating laboratory must establish its own mean values and CL for its test method with these QC materials. Temporary estimates of mean values and CL can be determined after 10 successive, independent measurements. *Slazyk WE, Hannon WH. Quality assurance in the newborn screening laboratory. In: Therrell BL Jr, editor. Laboratory methods for neonatal screening. Washington (DC): American Public Health Association, 1993:23-46.*